Common Ownership Statement to invoke 35 USC § 103(c).

As of the invention date for the current application, Hemocompatible Coatings on Hydrophobic Porous Polymers, application number 09/704,212, its inventors and the inventors for publication WO 01/45763 were subject to an obligation to assign these inventions to Advanced Cardiovascular Systems, Inc. Therefore, 35 USC § 103(c) disqualifies WO 01/45763 for use as prior art against the current application.

The remarks below follow the paragraph numbering of the outstanding Office Action.

Paragraph 2

The Office Action objects to claims 1, 17, 19 because of the following informalities: in claims 1 and 19, "thereby" is unnecessarily repeated; and in claim 17, "propanol" appears to be misspelled. Claims 1 and 19 have become claims 29 and 30; the correction appears in those claims.

In claim 17 "propanol" is now correctly spelled.

Please discontinue these objections.

Paragraph 4

The Office Action rejects claims 12-17 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants amend these claims to recite that the ranges specified in the claim have units of volume percent.

Please remove this rejection.

Discussion of Other Amendments

Claims 4, 5, 7, 8, 11, 12-18, and 20-22 now depend from different claims.

Applicants amend Claim 18 to additionally recite "or spray coating". Specification, page 14, line 21, supports this amendment.

Applicants cancel Claim 1 and replace it with Claim 29. Applicants cancel Claim 3. Except as discussed below, Claim 29 is intended to have the same scope as Claim 1. Applicants have reformatted and rearranged Claim 1 into Claim 29. The language in it more closely matches the specification at page 9, lines 15 through 17. As with the language from the specification, Claim 29 does not limit the order of addition of the first solvent, the second solvent, and the hemocompatible substance when the coating solution is prepared.

Applicants have added two limitations to Claim 1 during its transformation into Claim 29: (1) The limitations of Claim 3 now appear in Claim 29; and (2) Claim 29 now contains the limitation "provided that the hemocompatible coating is not subjected to a dialdehyde cross-linking or stabilization step before in vivo use."

The specification does not contain a literal basis for limitation (2). But of course a literal basis is not necessary. MPEP § 2173.05(i). "[T]here is no *in haec verba* requirement. . ." MPEP § 2163. All that is necessary is that the limitation "be supported in the specification through express, implicit, or inherent disclosure." MPEP § 2163.

Dialdehyde cross-linking requires that the hemocompatible coating have an accessible primary amine. Also, it requires that the hemocompatible substance retain its function after reaction with the dialdehyde cross-linking agent. These two characteristics will not hold true for most of the members of this hemocompatible coating genus. Specifically, it is impossible for the hydrophobic quaternary ammonium ions recited in Claim 9 to undergo dialdehyde cross-linking reaction because they do not have a primary amine.

Moreover, dialdehyde cross-linking is a specialized solution to an old problem, one now solved in other ways. The specification shows that Applicants have no need for such an esoteric stabilization step. Indeed, one of ordinary skill in the art would expect Applicants to teach uncommon steps if Applicants intended to disclose them. Such is not the case here. Therefore, a rational appraisal, from the point of view of one of ordinary skill in the art at the time the invention was made, would find that the limitation was inherently disclosed. The dialdehyde cross-linking step is an uncommon step that is unneeded for Applicants' modern coating method. The cross-linking step has only been demonstrated to be useful for very small set of hemocompatible coating substances -- heparin anions with alkylammonium cations. This step would interfere with, rather than enhance, virtually all of Applicants' disclosed embodiments. And it unequivocally will not work with some of Applicants' specifically disclosed embodiments. All of this adds up to a disclosure that communicates to one of ordinary skill in the art that the dialdehyde cross-linking step is not part of the invention. Therefore, since the limitation was inherently disclosed, explicitly reciting it in the claim does not amount to adding new matter.

To the extent that Applicants' disclosure is read to cover the sub-genus including the limitation introduced into claim 29 and the sub-genus without this limitation, Applicants choose to claim only that sub-genus with the limitation. Applicants are making clear that their claims do not read on another's teaching, they are not "creating an 'artificial sub genus' or claiming 'new matter'." In re Johnson and Farnham, 194 USPQ 187, 196 (CCPA 1977).

Applicants have deleted Claim 19 and replaced it with Claim 30 for much the same reason as discussed above. Note that Claim 19 does not have the limitation "provided that the hemocompatible coating is not subjected to a dialdehyde cross-linking or stabilization step before use." But Claim 19 does add a limitation to the types of solvents used as the first solvent. This list comes from Claim 7, as filed, except that "fluoropolymer-wetting cycloalkanes" are no longer recited. Thus, this amendment adds no new matter.

Paragraph 6

The Office Action rejects claims 1, 3, 5-11, 18-19, and 21-22 under 35 USC § 102(b) as being anticipated by Hsu, US patent number 4,871,357 (357).

Claim 29 replaces Claim 1; Claim 30 replaces Claim 19.

The 357 patent does not teach using a second solvent that enhances the solubility of the hemocompatible coating substance in a first-solvent-second-solvent mixture. While the patent does teach dissolving the heparin complex in a mixture of trifluoro, trichloro ethane and ethanol, it explicitly teaches that its heparin complex "ha[s] limited solubility in polar organic solvents such as methanol, ethanol and isopropyl alcohol". (Column 4, line 67 through column 5, line 2). Therefore, for this particular heparin complex, there is no evidence of record that ethanol "enhances the solubility of [the heparin complex] in the mixture of said first solvent and said second solvent".

The Office Action states that ethanol inherently dissolves the heparin complex due to its hydrophilic groups. But the Office Action ignores the remainder of the salt, notably the stearylkonium portion. The Office Action's contention that ethanol enhances the solubility of this complex belies the teaching of the 357 patent. (Column 4, line 67 through column 5, line 2). One of ordinary skill in the art does not add a solvent in which a solute has limited solubility if that person is interested in enhancing solubility. Please provide information showing that the solubility of this heparin complex is enhanced in trifluoro, trichloro ethane by adding ethanol because the only evidence of record is that the 357 heparin salt is more soluble in the haloalkane solvent than in ethanol.

The 357 patent disclosure shows that its heparin complex has "vastly superior hydrophobicity" compared to previous heparin complexes. (Column 4, line 13). Furthermore, the goal of the 357 patent is to make the hemocompatible coating complex more like the substrate surface to improve its affinity for the surface. (Column 7, lines 31-34). Therefore, 357 as a whole teaches matching the hydrophobicity of the coating to the substrate. Applicants use a solvent mixture to cause coating deposition regardless of the hemocompatible substance's affinity for the substrate.

Since the 357 patent does not teach a second solvent that enhances the solubility of the hemocompatible coating substance in a mixture of a first solvent and a second solvent, it does not anticipate these claims.

Please remove this rejection.

Since independent claims 29 and 30 are not anticipated by the 357 patent, the remaining paragraph-6 discussion regarding claims that depend from Claims 29 and 30 is moot. Therefore, Applicants take no position as to whether the patent teaches the limitations described in the Office Action. Applicants will explain why the patent lacks these limitations, should that become necessary.

Paragraph 7

Claims 1, 5-7, and 18 are rejected under 35 USC § 102(b) as being anticipated by Drumheller, US patent number 5,914,182 (182).

The 182 patent teaches sequential deposition of a first solvent followed by deposition of a second solvent. It does not teach creating a mixture of a first and second solvent and dissolving a hemocompatible substance in that mixture as required by claim 1, step c). Therefore, the patent does not anticipate these claims.

Please remove this rejection.

Paragraph 9

Claims 2, 4, 12-15, and 20 are rejected under 35 USC § 103(a) as being unpatentable over the 357 patent, discussed above.

The 357 patent does not teach a second solvent that enhances the solubility of the hemocompatible coating substance in a mixture of a first solvent and a second solvent, as is found in Claims 29 and 30, and therefore, in all claims that depend from Claims 29 and 30. The Office Action's obviousness-based rejection contained in paragraph 9 does not address this difference. Until an Office Action does so, prima facie obviousness has not been made out, and Applicants have no duty to address the rejection.

Please remove this rejection.

Since the 357 patent fails to teach the limitations described above, the remaining discussion in paragraph 7 regarding claims that are dependent from Claims 29 and 30 is moot. Therefore, Applicants take no position as to whether the patent teaches the limitations described in the Office Action. Applicants will explain why the patent lacks these limitations, should that become necessary.

Paragraph 10

The Office Action rejects claims 1-3, 5, 7-15, 17-19, and 22 under 35 USC § 103(a) as unpatentable over Eriksson, US patent number 4,118,485 (485), in view of van Tassel, US patent number 6,241,710 (710).

Claim 29 is now the lead independent claim. Eriksson (combined with VanTassel) does not teach a method where the hemocompatible coating is used without first undergoing a "dialdehyde cross-linking or stabilization step" as is set out in claim 29.

Without addressing this difference, this rejection fails to establish prima facie obviousness. Until a prima facie case of obviousness exists, Applicants need not answer this rejection to Claims 2, 3, 5, 7-15, 17, and 18.

Claim 30 has replaced claim 19. Claim 30 recites a list of solvent classes as originally recited in claim 7. Eriksson combined with VanTassel does not teach this list or members of this list, as the list is amended. Therefore, the prior art relied on for this rejection does not contain each and every element of claim 30. Nor does it contain an explanation of why the missing elements would be obvious. Therefore, this obviousness rejection is moot with regard to claim 30 and its dependent claims, because of the newly added limitation.

Please remove this rejection.

Since the 485 patent fails to teach the limitations described above, the remaining discussion in paragraph 7 regarding claims that depend from Claims 29 and 30 is moot.

Therefore, Applicants take no position as to whether the patent teaches the limitations described in the Office Action. Applicants will explain why the patent lacks these limitations, should that become necessary.

Paragraph 11

The Office Action rejects claims 1, 3-6, 8, and 18-21 under 35 USC § 103(a) as being unpatentable over PCT publication, WO 01/45763. This PCT publication has published as US patent application, US 2002/0193475 A1. Please see the above statement of common ownership of the current application and this reference. Therefore, this reference is not available as prior art against the current application.

Please remove this 103(a) rejection.

Since all claims are allowable, please issue a Notice of Allowability so stating.

If I can help you further or do anything to expedite the application's issuance, please contact me.

Date: 1/28/03

Respectfully submitted,

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"Marked-up Claims"

Claims

1. (cancelled)

2. (Amended Once) A method as in claim **[1]29** wherein said second solvent is dissolved in said first solvent in such quantity as to form an azeotropic mixture.

3. (cancelled)

4. (Amended Once) A method as in claim **[3]29** wherein said medical device is a stent.

5. (Amended Once) A method as in claim **[1]29** wherein said porous hydrophobic polymer includes at least one polymer selected from the group consisting of porous polyethylene, porous polypropylene, porous polyurethanes, porous polyacrylates, porous polymethacrylates and porous fluoropolymers.

6. *A method as in claim 5 wherein said porous fluoropolymer is expanded poly(tetrafluoroethylene).*

7. (Amended once) A method as in claim **[6]29** wherein said first solvent is selected from the group consisting of tetrahydrofuran, dioxane, fluoropolymer-wetting alkanes, fluoropolymer-wetting cycloalkanes, fluoropolymer-wetting ethers, fluoropolymer-wetting chlorofluorocarbons, fluoropolymer-wetting hydrofluorocarbons and mixtures thereof.

8. (Amended Once) A method as in claim **[1]29** wherein said hemocompatible coating substance comprises a complex of heparin with a hydrophobic counter ion.

9. *A method as in claim 8 wherein said hydrophobic counter ion is a hydrophobic quaternary ammonium ion.*

10. *A method as in claim 8 wherein said hydrophobic counter ion is selected from the group consisting of benzylalkonium ion and tridodecylmethylammonium ion.*

11. (Amended Once) A method as in claim **[1]29** wherein said second solvent is selected from the group consisting of organic alcohols, ketones, and mixtures thereof.

12. (Amended Once) A method as in claim **[1]29** wherein said second solvent is dissolved in said first solvent in an amount from about 0.00001**[%] volume percent[up]** to saturation.

13. (Amended Once) A method as in claim **[12]29** wherein said second solvent is dissolved in said first solvent in amount from about 0.1**[%] volume percent** to about 10**[%] volume percent**.

14. (Amended Once) A method as in claim **[13]29** wherein said second solvent is dissolved in said first solvent in amount from about 0.1**[%] volume percent** to about 2**[%] volume percent**.

15. (Amended Once) A method as in claim **[14]29** wherein said second solvent is dissolved in said first solvent in amount from about 0.5**[%] volume percent** to about 1**[%] volume percent**.

16. (Amended Once) A method as in claim **[1]29** wherein said first solvent is a mixture of isomers of dichloropentafluoropropane and said second solvent is methanol dissolved in said first solvent so as to form a [%] **volume percent** solution.

17. (Amended Once) A method as in claim **[1]29** wherein said first solvent **is** cyclohexane and said second solvent is n-prop**[o]a**n**[a]o**l dissolved in said first solvent **[so as]** to form a 5 [%] **volume percent** solution.

18. (Amended Once) A method as in claim **[1]29** wherein said hydrophobic polymer is coated with said hemocompatible coating substance by dip coating **or spray coating**. {specification page 14, line 21}

19. (cancelled)

20. A method as in claim **[19]30** wherein said medical device is a stent.

21. A method as in claim **[19]30** wherein said porous hydrophobic polymer comprises expanded poly(tetrafluoroethylene).

22. A method as in claim **[19]30** wherein said hemocompatible coating substance is a complex of heparin with a hydrophobic counter ion.